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Kenneth T. Heruth

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MEDTRONIC, INC.  
710 MEDTRONIC PARKWAY NE  
MINNEAPOLIS, MN 55432-9924

EXAMINER

MACNEILL, ELIZABETH

ART UNIT

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**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.



## **DETAILED ACTION**

### ***Claim Rejections - 35 USC § 102***

1. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

2. Claims 1 and 4-7 are rejected under 35 U.S.C. 102(e) as being anticipated by Pollicker et al (US 7,330,753).

Pollicker teaches a method of measuring an electrical activity of the gastrointestinal tract (electrode 74,100); estimating a quantity of food consumed by the patient (Col 4, paragraph at line 15); and delivering a therapy (electrical stimulation, Abstract) as a function of the quantity of food. See Col 7, first full paragraph, and Col 10 paragraph at line 35. As to claim 5, see Col 7 line 23, "The antral electrode set typically includes two antral electrodes, adapted to be coupled to two sites of the antrum, and the control unit is adapted to identify a measure of electrical impedance between the two sites of the antrum." As to claim 6 and 7, the movements of the GI tract are considered an "activity" or "physical motion" of the patient.

### ***Claim Rejections - 35 USC § 103***

3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

4. Claims 1,2,4-8, 10,11, and 13-22 are rejected under 35 U.S.C. 103(a) as being unpatentable over Stultz (US 2002/0156462) in view of Pollicker as applied above.

Stultz teaches delivering medication in response to a measured physiological parameter (P0012). Stultz teaches measuring core body temperature, physical activity, and heart rate. Stultz delivers one or more drugs from an implantable pump (Fig 3) with a processor (34) and sensors (18a-18m).

Stultz teaches "The sensor may sense the glucose level present in body fluids, and in response to sensing a glucose level that is out of range of predetermined acceptable levels, cause the pump to take appropriate corrective action by delivering an appropriate medication(s)" (P0029). It is well known in the art that insulin and glucagon are known medications that are appropriate for the treatment of glucose levels (See also MAULT (US 2003/0208113, P0038). Stultz does not teach that the processor estimates the quantity of food consumed by the patient.

Pollicker teaches a method of measuring an electrical activity of the gastrointestinal tract (electrode 74,100); estimating a quantity of food consumed by a patient (Col 4, paragraph at line 15); and delivering a therapy (electrical stimulation, Abstract) as a function of the quantity of food. See Col 7, first full paragraph, and Col 10 paragraph at line 35.

It would have been obvious to one ordinary skill in the art at the time the invention was made to deliver a medication in response to estimating the quantity of food consumed by the patient since Stultz teaches delivery of medications in response to sensed parameters and Pollicker teaches estimating a quantity of food to deliver a therapy to the patient. Estimating the quantity of food consumed is an alternative parameter and it has been held that simple substitution of one known element (GI tract mobility) for another (any of the parameters taught by Stultz, temperature, heart rate, etc) is within the skill of an ordinary worker in the art.

### ***Response to Arguments***

5. Applicant's arguments have been considered but are moot in view of the new ground(s) of rejection.

### ***Conclusion***

6. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of

the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to ELIZABETH R. MACNEILL whose telephone number is (571)272-9970. The examiner can normally be reached on 9:00-5:30 M-F.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Kevin Sirmons can be reached on (571) 272-4965. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Elizabeth R MacNeill/  
Examiner, Art Unit 3767  
/Kevin C. Sirmons/  
Supervisory Patent Examiner, Art Unit 3767